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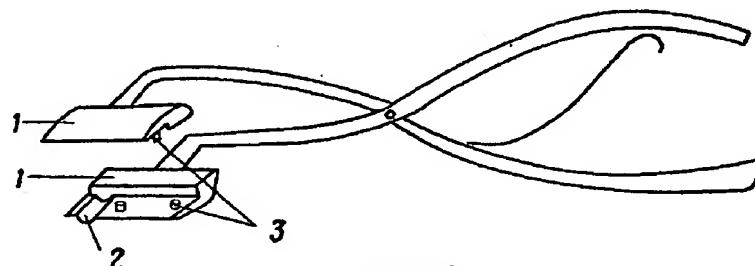
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ЖИМ И ИНСТРУМЕНТ ДЛЯ ЕГО НАЛО-
ЖЕНИЯ

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((57) Изобретение предназначено для хирургии. Цель изобретения — улучшение фиксации зажима на сосудах паренхиматозных органов и уменьшение травматичности. Инструмент для наложения кровоостанавливающего зажима содержит рабочие губки 1 с выемкой 2, выступ 3. Кровоостанавливающий зажим имеет паз, плечо. Его помещают между рабочими губками 1 в выступы 3 так, чтобы плечо зажима разместилось над выемкой 2 и таким образом зажим фиксируют на инструменте. После установления зажима между губками 1 вводят конец сосуда, затем губки зажима смыкаются. 2 с. л. ф-лы, 4 ил.



Фиг. 2

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Изобретение относится к медицине, а именно к хирургическим инструментам, и может быть использовано для остановки кровотечения из крупных сосудов при их пересечении при выполнении операций.

Цель изобретения — улучшение фиксации зажима на сосудах паренхиматозных органов и уменьшение травматичности при наложении зажима.

На фиг. 1 изображен кровоостанавливающий зажим, общий вид; на фиг. 2 — инструмент для наложения кровоостанавливающего зажима, общий вид; на фиг. 3 — кровоостанавливающий зажим в инструменте для наложения (в раскрытом виде); на фиг. 4 — кровоостанавливающий зажим на сосуде.

Инструмент для наложения кровоостанавливающего зажима содержит рабочие губки 1 с выемкой 2, выступ 3, кровоостанавливающий зажим 4 имеет паз 5 и плечо 6.

Устройство работает следующим образом. Кровоостанавливающий зажим 4 помещают между рабочими губками 1 в выступы 3 так, чтобы плечо 6 зажима 4 разместилось над выемкой 2. Тем самым осуществляют фиксацию зажима 4 на инструменте. После того, как кровоостанавливающий зажим 4 установлен в инструменте, между губками 1 вводят конец сосуда.

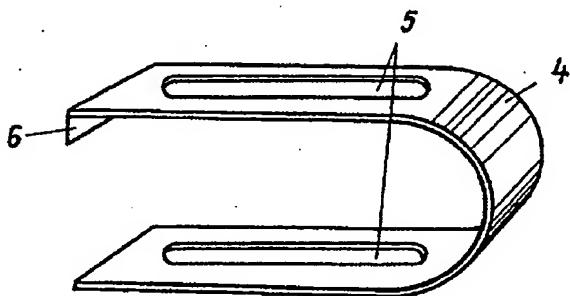
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Затем рабочие губки 1 кровоостанавливающего зажима смыкаются. При этом стеки сосуда входят в продольные пазы 5 и выбухают в них в силу своей эластичности, а плечо 6 на одной из губок 4 входит в выемку 2 и загибается. Происходит зажатие и фиксация зажима на сосуде.

Формула изобретения

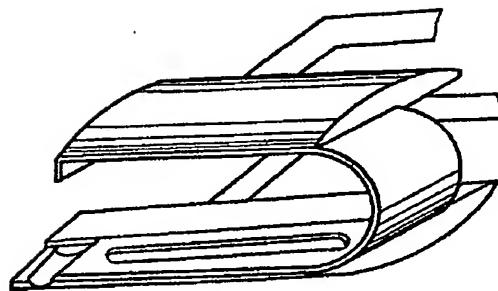
1. Кровоостанавливающий зажим в виде изогнутой U-образной металлической пластины с фиксатором, отличающийся тем, что, с целью улучшения фиксации зажима на сосудах паренхиматозных органов, в пластине выполнены продольные прорези, а фиксатор краев пластина выполнен в виде отогнутого плеча.

2. Инструмент для наложения кровоостанавливающего зажима, содержащий шарнирно соединенные бранши с рабочими губками, отличающийся тем, что, с целью уменьшения травматичности при наложении кровоостанавливающего зажима на паренхиматозные органы, рабочие губки выполнены в виде удлиненных пластин, имеющих по наружной поверхности звуженную форму по толщине и установленных под прямым углом к продольной оси бранш, на внутренних поверхностях пластин выполнены выступы в виде шпилек, а на одной из губок — выемка.

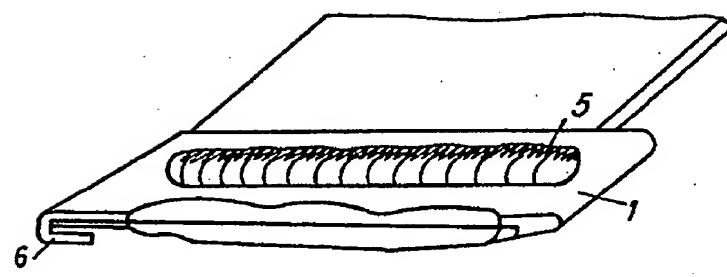


Фиг. 1

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фиг.3



фиг.4

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Technical Report

Safety Evaluation of Laparoscopically Applied Clips

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ABSTRACT

We have evaluated *in vitro*, the security of laparoscopically applied clips, through two commercially available clip applicators: the Endo Clip II (US Surgical) and the Ligaclip (Ethicon). The clip performance was tested with respect to dislodgment and leakage. Dislodgment was attempted both transversely and at 45° with respect to the main axis of the tubular structures tested. The mean maximum force ($N = 24$) necessary to dislodge a clip applied to silicone tubing (2.1, 2.4, 3.2 mm o.d.) and porcine vascular tissue was measured. The maximum force needed to transversely dislodge a clip applied to silicone tubing, ranged from 262 ± 9 g (2.1 mm) to 315 ± 11 g (3.2 mm) for the Endo Clip II applicator, while the values for the Ligaclip were 220 ± 28 g (2.1 mm) and 273 ± 11 g (3.2 mm), respectively. To achieve dislodgment at 45° pull, corresponding forces of 294 ± 8 g (2.1 mm) and 369 ± 14 g (3.2 mm) for the Endo Clip II, and 254 ± 14 g (2.1 mm) and 297 ± 13 g (3.2 mm) for the Ligaclip ($N = 24$) were required. Transverse dislodgment forces, for clips applied to tissue, were 556 ± 146 g for the Endo Clip II and 356 ± 170 g for the Ligaclip ($N = 6$). Leakage tests were also performed under pulsatile blood circulation at mean pressure of approximately 800 mm Hg. No tested clips applied to either silicone tubing or tissue allowed for any blood leakage. The dislodgment test showed that the Endo Clip II exhibits superior performance compared to the Ligaclip, based on the fact that it requires more force for transverse and semiaxial dislodgment. In the leakage test, both clip applicators performed equivalently.

INTRODUCTION

LAPAROSCOPIC SURGERY already represents a major advance in modern surgery and has opened new avenues in minimally invasive surgery. The ever-expanding number of laparoscopic techniques and the volume of cases performed daily have triggered an impressive wave of new instrumentation geared to accommodate the various needs of the laparoscopic surgeon. However, due to this rapid evolution in the field, very few published data are available regarding the evaluation and design optimization of the laparoscopic instruments. A properly designed instrument not only facilitates the surgeon, but also minimizes possible risk to the patient.

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Serious complications of laparoscopic procedures have been reported in a number of studies including cystic artery bleeding and bile leakage.³⁻⁹ In a number of clinical studies clip dislodgment, slipping and migration have been reported.^{2,11,14-18} Such clip misfunctions have led to postoperative complications such as biliary ascites, biliocutaneous fistula, and obstructive jaundice. It has been suggested that inappropriate application by the surgeon, or accidental dislodgment of the clips, during laparoscopy may be partially responsible for these complications.⁷ Insufficient grasp of the tubular structures by the clips may also contribute to complications due to bleeding or bile leakage. Therefore, it is important to evaluate the security of laparoscopically applied clips.

Little information is available regarding the performance of laparoscopic clip applicators. Previous experimentation¹⁰ suggests that among two popular clip applicators, the Ligaclip EMCA applicator (Ethicon) and the Endo Clip applicator (US Surgical), the former is more secure than the latter. The results were based on transversal and axial dislodgment experiments. The clips were applied on either silicone tubing of 2.4 mm o.d., or on porcine mesenteric vessels. Recently, Beltran et al.¹⁹ compared the security of the Ligaclip and Endo Clip II applicators with respect to axial and transverse dislodgment. The experiments were conducted on both silicone tubing (2.4 mm o.d.) and porcine cystic ducts. It was found that the Endo Clip II clips required significantly greater dislodgment force than the Ligaclip clips. In another study,¹ the occlusive strength of the Endo Clip applicator (US Surgical) versus suture ligation was evaluated for the ligation of the renal artery in a porcine model. *In situ* pressure studies suggested that occlusion of the renal artery with three clips is as secure as occlusion with standard 2-0 and 0-silk ligatures. The hemostatic and tissue reactivity of titanium clips (US Surgical) was also tested in an animal model, where clips were applied distally and proximally to the midpoint of transected fallopian tubes. Satisfactory uniform hemostasis was achieved. Finally, the holding power of titanium clips has also been tested against the holding power of absorbable polymeric clips.¹³

To further evaluate the performance of laparoscopic clip applicators, we have performed both dislodgment and leakage tests on silicone tubing and porcine arterial tissue, with two widely used clip applicators: the Endo Clip II and Ligaclip applicators. Tests of dislodgment at 90° (transversal) and at 45° (semiaxial) with respect to the main tubular axis were performed. Three different o.d. sizes of silicone tubing were used for each direction of dislodgment. We also performed leakage tests for both silicone tubing of three different sizes and tissue. It was felt that in addition to the dislodgment test, this is an important test in order to evaluate the hemostatic capability of the applied clips.

MATERIALS AND METHODS

Disposable endoscopic rotating multiclip applicators were obtained from US Surgical Corp (Norwalk, CT) and Ethicon Inc (Somerville, NJ) as quality assured products. The two particular models of clip applicators tested were the Auto Suture Endo Clip II applicator, from US Surgical, and the Ligaclip ERCA clip applicator from Ethicon. The applicators contained 20 medium-large titanium clips of rectangular wire. In both models the clip length was approximately 9 mm when closed. The inner span, at the tip of the clip, was approximately 4.6 mm for the Endo Clip and 4.0 mm for the Ligaclip.

The experiments were performed *in vitro*. The clips were applied to both silicone tubing obtained from Cole Parmer (Chicago, IL), and freshly excised porcine carotid artery segments. To evaluate the holding power of the applied clips on structures of different sizes, tubing of 2.1, 2.4, and 3.2 mm o.d. was used. The wall thickness for all tubing sizes was 0.8 mm. The silicone tubing was chosen because of its texture similarity to the cystic artery.

Dislodgment test on silicone tubing and tissue

Dislodgment test on silicone tubing. Test segments of tubing were placed, horizontally, on top of two posts placed 5 cm apart. The tubing was securely clamped on each holder, as shown in Figure 1. No longitudinal tension was applied during mounting of the test segments. The clips were applied transversely with respect to the tubing long axis, midway between the holding posts. During clip application the clip applicators were placed on a metal holder (not shown in Fig. 1) located directly above the tubing. The holder was inclined, with respect to the vertical direction, by approximately 14.8° for the Endo Clip II and 13.5°

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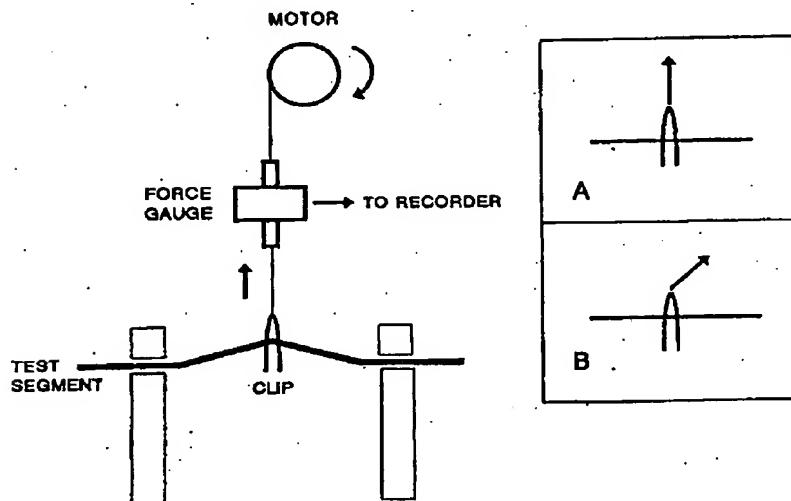


FIG. 1. Setup for transverse (A) and semiaxial (B) clip dislodgment test for both silicone tubing and tissue.

for the Ligaclip. This inclination accounts for the angle between the jaws of the applier and the direction of its shaft. This arrangement allowed for consistent orientation and placement of the clips throughout the experimentation.

Prior to clip application a loop of 000 silk suture was placed through the heel of the clip. The loop was later used to pull the clip to dislodge it from the tubing. Each clip was applied by squeezing the handle of the applier, firmly, until the motion was prevented by the applicator. The applier was then removed and the loop was attached to one side of a calibrated force gauge. The force gauge (Model BG10) was obtained from Mark-10 (Hicksville, NY) and had maximum capacity of 10 lb. The opposite side of the force gauge was attached to a stainless-steel wire (250 μm o.d.), which, in turn, was connected to a motor (model S57-102-MO, Compumotor, Rohnert Park, CA). The motor was located directly above the tubing in such a way that the clip, loop, gauge, and wire formed a straight line perpendicular to the long axis of the tubing.

Clip dislodgment tests were performed by pulling the clip away from the tubing, either transversely or at 45° with respect to its long axis. The latter test was conducted with the clip applier holder and the holding posts rotated by 45°. The two different directions of pull are shown in the inset of Figure 1. The speed of the motor was set via a Compumotor TM8 thumbwheel adaptor interfaced to a Compumotor SX6 drive module. Each test was conducted at pulling speed of 10 mm/sec. The maximum force required to dislodge a clip was recorded from the digital display of the controller connected to the force gauge. During dislodgment, the analog output of the force gauge was also monitored on a strip chart recorder. The transverse and semiaxial dislodgment force was calculated as the mean of 24 data points obtained from each instrument, for each dislodgment orientation, and each tubing size. Following each trial, the tubing was released, shifted by approximately 8 cm, and clamped again. This ensured that the next clip was applied to an unused portion of the tubing. Eight Ligaclip (Lot No:DJ13PB) and eight Endo Clip II appliers (Lot No:N4246) were used.

Dislodgment test on tissue. Freshly excised, porcine carotid artery portions were used. Experimentation ensued immediately following excision. The tissue was placed in a bath of isotonic 0.9% NaCl solution. Tissue segments during testing were kept moist through saline flushing. The size of the segments varied from approximately 3.0 to 5.0 mm o.d. Testing was performed with the setup described previously and shown in Figure 1. The tissue was subjected only to transverse dislodgment test. The transverse dislodgment force was calculated as the mean of six measurements for each instrument.

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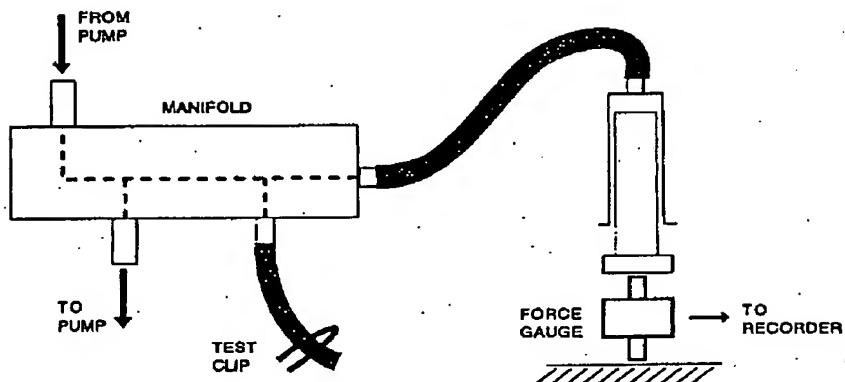


FIG. 2. Setup for evaluation of the hemostatic ability of clips. The clips were applied to either silicone tubing or tissue. The peristaltic pump maintained a mean pressure of ~800 mm Hg.

Leakage test on silicone tubing and tissue

Leakage test on silicone tubing. This test was performed with the setup shown in Figure 2. Thirty five milliliters of freshly withdrawn, heparinized porcine blood was circulated by a peristaltic pump in a closed loop, thus creating pulsatile flow and simulating a physiological environment. The force gauge used in the dislodgment test was used here in the compression mode. The gauge was compressed by the piston of a 3-cm³ glass syringe, which, in turn, was connected, through the manifold, to the circulating blood. The pressure was then calculated by dividing the readout of the force gauge by the cross section of the syringe piston. The tubing was connected via a luer lock attachment to one of the ports of the manifold, as shown in Figure 2. After bleeding the system of air, the other free end of the tubing was clipped transversely. The

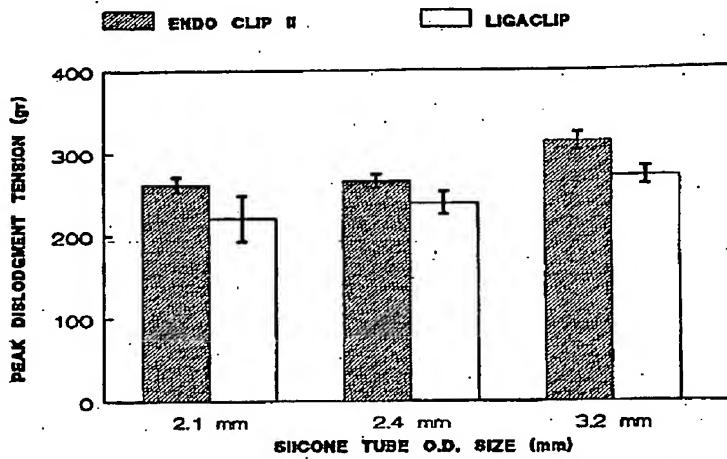


FIG. 3. Peak transverse dislodgment tension vs silicone tubing size (transverse pull, $N = 24$). The mean peak dislodgment tension for the Endo Clip II is significantly higher than the mean peak dislodgment tension for the Ligaclip for all tube sizes ($p < 0.001$). The increase in mean tension between 2.4 and 3.2 mm was statistically significant for both appliers tested ($p < 0.001$).

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pump was adjusted so that a mean pressure of approximately 800 mm Hg was achieved. This pressure is well above any expected mean physiological pressure. Under this extreme pressure, each applied clip was tested for 15 min. During testing, the clamped portion of the tubing was visually inspected for gross leakage. At the end of each test the clipped site was also inspected under 20 \times magnification for microscopic leakage evaluation. Six clips from each manufacturer and for each tubing size (2.1, 2.4, 3.2 mm) were applied. Prior to applying a new clip, the old clipped site was cut and blood was allowed to leak from the tubing. In all trials no blood coagulation was found in the stagnant blood column of any tube. We therefore conclude that full measured pressure was applied to each clip. Each new clip was applied to a new tubing segment.

Leakage test on tissue. This test was performed with the same setup described above. One end of the tissue segment was connected to the circuit by ligation on one of the ports of the manifold. Experimentation then proceeded in a similar fashion as described in the previous section for the silicone tubing. The type and handling of tissue were identical as in the dislodgment tests.

Statistical analysis

Throughout, data are given as mean (\pm SD). Statistical analysis was performed by Mann-Whitney rank-sum test. Transverse and semiaxial clip security was assessed by comparison of pairs of dislodgment forces for the two instruments for the different tube sizes and dislodgment directions. Clip dislodgment security of tissue was accessed by comparison of the transverse dislodgment forces for the two instruments.

RESULTS

Dislodgment test on silicone tubing and tissue

The results of the dislodgment tests are shown in Figures 3 to 5. The numerical results are shown in Tables 1 to 3. Figure 3 shows the results from transverse dislodgment on silicone tubing for all sizes used. Figure 4 presents the corresponding results for 45° pull. For all tubing sizes and dislodgment orientations,

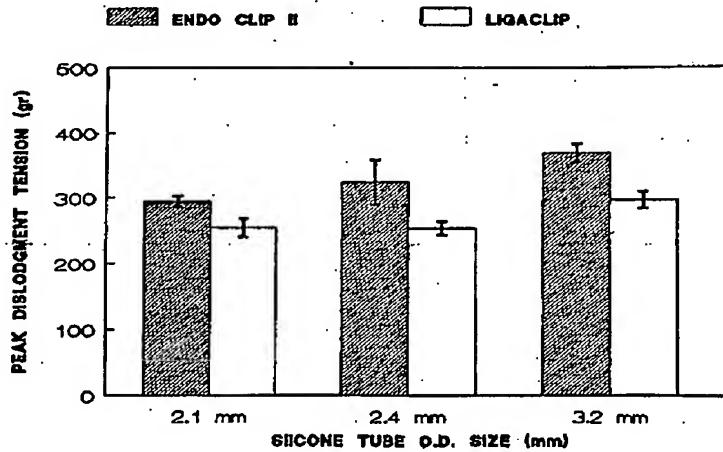


FIG. 4. Peak semiaxial dislodgment tension vs silicone tubing size (45° pull, N = 24). The mean peak dislodgment tension for the Endo Clip II is significantly higher than the mean peak dislodgment tension for the Ligaclip for all tube sizes ($p < 0.001$). The increase in mean tension between 2.4 and 3.2 mm was statistically significant for both applicators tested ($p < 0.001$).

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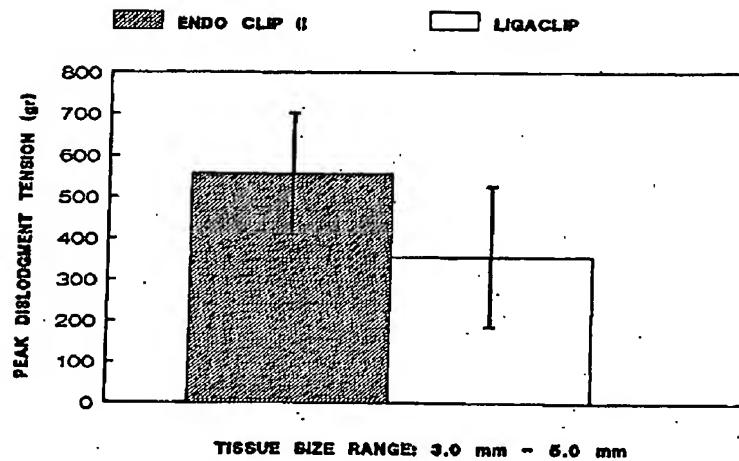


FIG. 5. Peak transverse dislodgment tension for porcine vascular tissue (transverse pull, $N = 6$). The mean peak transverse dislodgment tension was significantly higher for the Endo Clip II than the Ligaclip ($p < 0.03$).

the mean maximum force for the Endo Clip II was significantly higher than the mean maximum dislodgment force for the Ligaclip ($p < 0.001$). A force increase of 19, 11, and 15% was observed for the 2.1, 2.4, and 3.2 mm tubing sizes, respectively, for transverse dislodgment. While a corresponding force increase of 16, 28, and 24% was observed for semiaxial dislodgment.

In Figure 5, the results of the clip dislodgment measurements on tissue are presented. The maximum observed force for the Endo Clip II applier was significantly higher than the corresponding force for the Ligaclip ($p < 0.03$).

From Figures 3 and 4, it can also be seen that the mean maximum force for dislodgment generally increases with the tubing size for both type of instruments tested. The observed increase of the mean maximum force ranged from 17 to 25% as the tubing size was increased from 2.1 to 3.2 mm o.d. The increase in mean force between 2.4 and 3.2 mm was statistically significant ($p < 0.001$) for both applicators tested. Additionally, as shown in Figures 3 and 4, there is a systematic increase of the required force from the transverse to the semiaxial dislodgment, for the same tubing size and for both instruments. This increase ranged from 6 to 22%.

Leakage test on silicone tubing and tissue

No leakage was observed either macroscopically or microscopically. Neither the Endo Clip II nor the Ligaclip clips leaked at pressures far exceeding physiological values.

TABLE I. CLIP SECURITY ON SILICONE TUBING (TRANSVERSE PULL)

	Peak tension (g) (N = 24)		
	Endo Clip II	Ligaclip	ERCA
Tubing size	2.1 mm	2.4 mm	3.2 mm
Mean	262/220	266/239	315/273
SD	9/28	8/14	11/11
Min	252/128	252/210	292/250
Max	282/248	284/258	332/290

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TABLE 2. CLIP SECURITY ON SILICONE TUBING (45° PULL)

	Peak tension (g) (N = 24)		Endo Clip II/Ligaclip ERCA
	2.1 mm	2.4 mm	
Tubing size			3.2 mm
Mean	294/254	324/254	369/297
SD	8/14	34/10	14/13
Min	280/218	282/234	348/280
Max	304/276	444/274	398/326

DISCUSSION

The aim of this study was to evaluate the occlusive strength and security against dislodgment for laparoscopically applied clips, by comparing two commercially available clip applicators. Our data document a safety profile with respect to occlusion strength for both the Endo Clip II and the Ligaclip applicators. These results are in agreement with another pertinent study of Kerbl et al.¹ In this study, the occlusion of porcine renal arteries with three titanium 9 mm clips, applied with the Endo Clip, showed no signs of leakage at supraphysiological pressures as high as 3100 mm Hg. Anatomical variations as well as acute or inflammatory changes of the normal anatomy may affect the safety margins of clip application. Our data suggest that within the range of tubing and tissue sizes used, the occlusive strength of the clips is not affected.

Our results indicate greater transverse and semiaxial dislodgment security for the Endo Clip II applicator than the Ligaclip. At 2.4-mm tube size, and transverse dislodgment, we report a mean average transverse force of 239 ± 14 g for the Ligaclip and 266 ± 8 g for the Endo Clip II ($N = 24$). Under similar experimental conditions, Beltran et al.¹⁹ report a force of 218 ± 17 g for the Ligaclip and 252 ± 19 g for the Endo Clip II ($N = 36$), in good agreement with our results. In a similar study, comparing the Ligaclip and the Endo Clip applicators, Nelson et al.¹⁰ reported a mean transverse force of 273 ± 4 g for the Ligaclip and 185 ± 7 g for the Endo Clip ($N = 6$). Our results indicate a significantly improved performance of the Endo Clip II versus the earlier Endo Clip design. Similarly, in our study, the force required to remove a clip was always significantly higher for the Endo Clip II than the Ligaclip, for all other sizes and both dislodgment directions ($p < 0.001$). Direct comparison of our data for tube sizes of 2.1, 3.2, and semiaxial dislodgment with other studies is not possible since such data have not been published. The observed increase of the required dislodgment force from the Ligaclip to the Endo Clip II applicator ranged from 11 to 28% for the tubing, and it was approximately 55% for the tissue tested.

The dislodgment tests have revealed several characteristics pertinent to the direction of attempted dislodgment and to the particular type of clip applicators tested. The semiaxial force required to dislodge the clips from the silicone tubing was found to be always higher ($p < 0.001$) than the force required for transverse dislodgment. This was true for both clip applicators and all tube sizes used. The increase in force value ranged from approximately 10 to 20%. Similar results were obtained by Nelson et al.¹⁰ and Klein et al.¹³ where for purely axial pull, the recorded axial force was approximately twice as much as the transverse force. The reason for this increase can be seen in the fact that during semiaxial pull only part of the applied force

TABLE 3. CLIP SECURITY ON TISSUE (TRANSVERSE PULL)

	Peak tension (g) (N = 6)	
	Endo Clip II	Ligaclip ERCA
Mean	556	356
SD	146	170
Min	356	104
Max	760	514

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is used directly for dislodgment. The axial component of this force is used for shifting of the clip along the main axis of the structure and simultaneous distortion of the tube around the point of application due to torque. The practical implication of this result is that transverse traction requires the least amount of force for dislodgment. Thus, surgical maneuvers characterized by instrumental movements directed axially to the clipped structures, may be less dangerous with respect to clip dislodgment, than maneuvers leading to movements transverse to the clipped structures.

In conclusion, we have conducted dislodgment and occlusion tests to evaluate the security of clip application for two commercially available laparoscopic clip appliers: the Ligaclip applier and the Endo Clip II applier. The tests were performed on silicone tubing of various sizes and freshly excised porcine aortic tissue. Both appliers exhibited significant occlusion strength even at supraphysiological pressures. However, the Endo Clip II applier was found to perform superiorly to the Ligaclip with respect to both transverse and semiaxial dislodgment.

ACKNOWLEDGMENT

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